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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,821	10/16/2003	Eric Wickstrom	08321-0128US1	2530

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,821

Applicant(s)

WICKSTROM ET AL.

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4, 6-20, 24-39, 83 and 85 in part, and claims 40-56, 76-82, and 86 in full, drawn to a diagnostic detection method comprising, (1) contacting cells of a subject that contain transcripts comprising a target nucleic acid sequence with a compound comprising a diagnostic moiety conjugated to at least one PNA and at least one targeting moiety, wherein the PNA comprises a base sequence that is complementary to a target nucleic acid sequence, such that the compound binds to the cells via the targeting moiety and is internalized by the cell; (2) allowing the PNA to bind to the target nucleic acid sequence and retain the compound inside the cell; and (3) detecting the compound within the cells, classified for example in class 435, subclass 6.
2. Claims 1-3, 5-12, 21-39, 83, and 85 in part, and claims 57-68, and 87 in full, drawn to a therapeutic method comprising (1) contacting cells of a subject that contain transcripts comprising a target nucleic acid sequence indicative of a pathological state with a compound comprising therapeutic moiety conjugated to at least one PNA and at least one targeting moiety, wherein the PNA comprises a base sequence that is complementary to a target nucleic acid sequence, such that the compound binds to the cells

via the targeting moiety and is internalized by the cell; (2) allowing the PNA to bind to the target nucleic acid sequence and retain the compound inside the cell, wherein the presence of the compound within the cell inhibits cell growth or causes death of the cell, classified in class 514, subclass 44.

Claims 69-75 link inventions 1 and 2. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 69-75. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The inventions are distinct, each from the other because of the following reasons:

Inventions 1 and 2 are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making

and method of using. The product claims will be examined along with the elected invention (MPEP § 806.05(i)).

Election of Species

This application contains claims embracing a vast number of structurally, functionally, and patentably distinct compositions. These embodiments are clearly distinct because they require non-coextensive searches, and the various compositions have different structures and functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

First an election is required between polymeric diagnostic and polymeric therapeutic moieties, consonant with the group restriction set forth above. These embodiments are clearly distinct because they require non-coextensive searches, and the compositions have different structures and functions.

Next an election of a specific PNA is required, i.e. one that targets one disclosed RNA transcript, e.g. selected from the group set forth in claim 33: K-RAS, c-MYB, BCR-ABL, p53, CCND1, HER2, MYC, c-fms, c-kit, c-met, c-trk, c-neu, c-src, c-fes, c-abl, c-fgr, c-yes, c-erbA, c-evi-1, c-gli-1, c-maf, c-lyl-1, c-ets, c-fos, c-jun, c-myb, b-myb, N-myc, L-myc, c-rel, c-vav, c-ski, and c-spi.

Applicant must also elect a single disclosed targeting moiety e.g. from those recited in claim 34 (i.e. a protein, a glycoprotein, a peptide, a steroid, a carbohydrate, a

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lipid or a vitamin). Should applicant elect a protein, then a further election of a specific disclosed protein is required, e.g. an antibody, transferrin, epidermal growth factor (EGF, i.e. urogastrone), platelet-derived growth factors, thyrotropin releasing hormone (TRH); nerve-growth factor (NGF); an HIV viral antigen; alpha₂-macroglobulin; thrombin; transforming growth factor-alpha (TGF-alpha); heregulins (HRGs); alpha fetoprotein (AFP), IGF1, ST, the disulfide-bonded D-peptide Gly-Cys-Ser-Lys-Ala-Pro-Lys-Leu-Pro-Ala-Ala-Leu-Cys or the disulfide-bonded D-peptide Cys-Ser-Lys-Ala-Pro-Lys-Leu-Pro-Ala-Ala-Tyr-Cys. Alternatively applicant could elect folate, arachidonic acid, or thiodothyronine as a targeting moiety.

Applicant must then decide whether to include in the elected invention a chelant. If Applicant elects to include a chelant, then a further election of a disclosed chelant from e.g. those disclosed in claims 25 and 27 is required (i.e. N₂S₂ chelants, N₃ chelants, N₂S₃ chelants, N₂S₄ chelants, N₃S₃ chelants, N₄ chelants, NS₃ chelants, ethylenediamine-N,N,N',N'-tetraacetic acid (EDTA); N,N,N',N'',N'''-diethylene-triaminepentaacetic acid (DTPA); 1,4,7,10-tetraazacyclododecane-N,N',N'',N'''-tetraacetic acid (DOTA); 1,4,7,10-tetraazacyclododecane-N,N',N''-triacetic acid (DO3A); 1-oxa-4,7,10-triazacyclododecane-N,N',N''-triacetic acid (OTTA); trans(1,2)-cyclohexanediethylene-triamine-pentaacetic acid (CDTPA); 1-oxa-4,7,10-triazacyclododecanetriacetic acid (DOXA); 1,4,7-triazacyclononanetriacetic acid (NOTA); and 1,4,8,11-tetraazacyclotetradecanetetraacetic acid (TETA).

If Applicant elects to include a chelant, then Applicant must also then decide whether to include complexed metal ion. Should Applicant choose to include a

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complexed metal ion, then a further election of a disclosed metal ion is required, e.g. from those listed in claims 15, 16, 18, 20, 23.

Applicant must also decide whether or not to include a dendrimer, and if so what structure (starburst dendrimers, cascade dendrimers controlled hyperbranched dendrimers or random hyperbranched dendrimers) and composition (polyamidoamine (PAMAM) dendrimer, a polypropylamine (POPAM) dendrimer, a polyether (PE) dendrimer or a polyethyleneimine (PEI) dendrimer) of dendrimer.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-

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272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
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